Camber Spine Technologies

510(k) Summary
Traditional 510k

as required by section 807.92(c).

Orthros Posterior Stabilization System
K133366
Prepared 3/5/14

Submitter:	Camber Spine 90 S. Newtown Street Rd., Suite #10 Newtown Square, PA 19073
Contact Person	Dan Pontecorvo President Phone: 484-420-4219, Fax: (484) 318-8031 Email: delvalsyn@comcast.net
Trade Name	Orthros Posterior Stabilization System
Common Name	Pedicle Screw System
Device Class	Class III
Classification Name and Number	Orthosis, Spondylolistheses Spinal System , 21 CFR 888.3070 Orthosis, Spinal Pedicle Fixation, 21 CFR 888.3070
Classification Panel:	Orthopedic
Product Code	NKB , MNI , MNH, KWQ
Reason for 510k	New Device
Predicate Devices	Corelink Tiger Spine System (K121728), Globus Medical Revere Stabilization System (K061202), Globus Medical Creo Stabilization System (K124058), Medtronic CD Horizaon Legacy 4.5mm System (K113395) and Synthes Pagea Monoaxial System (K052151)

Device Description	Orthros Posterior Stabilization System consist of a variety of shapes and sizes of rods, monoaxial screws, polyaxial screws, locking caps and associated manual surgical instruments. Implant components can be rigidly locked into a variety of configurations for the individual patient and surgical condition. Polyaxial screws are intended for posterior and anterior use. Rods and monoaxial screws may be used anteriorly or posteriorly. Locking caps and locking set screws are used to connect screws to the rod. The rods are composed of titanium alloy, as specified in ASTM F136. All other implants are composed of titanium alloy, as specified in ASTM F136.
Intended Use	Orthros Posterior Stabilization System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral/iliac spine (T1-S1/Ilium): degenerative disc disease (defined as discogenic back pain with degeneration of disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). In addition, Orthros Posterior Stabilization System is intended for treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.

Materials:	All implants are manufactured out of Titanium Alloy, specifically TAV- per ASTM F136. Supporting instrumentation is manufactured out of medical grade Stainless Steels including: 303, 17-4, 420, 455 & 465 alloys. Aluminum, specifically 6061-T2 is also used on some instruments.

Statement of Technological Comparison	Orthros Posterior Stabilization System and its predicate devices have the same indications for use, similar design, principles of operation and test results. Both devices are manufactured using materials with a long history of use in orthopedic implants.

Nonclinical Test Summary	The following tests were performed to demonstrate that the Orthros Posterior Stabilization System System is substantially equivalent to other predicate devices. • Static Axial Compression Bend Test per ASTM F1717-13 • Static Axial Torsion Test per ASTM F1717-13 • Dynamic Axial Compression Bend Test per ASTM F1717-13 • Screw Pullout Testing per ASTM F543-07 The results of these studies showed that the Orthros Posterior Stabilization System met the acceptance criteria.
Clinical Test Summary	No clinical tests were performed.

Sterilization Information	
Implants	The Implant will be shipped non-sterile and will be autoclaveable, validation testing of the process was conducted (using the half-cycle method) to a Sterility Assurance Level (SAL) of 10-6 per ISO 17665.
Instruments and Case	The instrument and case will be shipped non-sterile and will be autoclaveable, validation testing of the process was conducted (using the half-cycle method) to a Sterility Assurance Level (SAL) of 10-6 per ISO 17665.

Conclusion	The Orthros Posterior Stabilization System is substantially equivalent to its predicate devices. This conclusion is based upon the fact the Orthros Posterior Stabilization System and its predicate devices have the same indications for use, have a similar design, principles of operation and technical characteristics, similar test results, and any differences do not raise new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 8, 2014

Camber Spine Technologies
Mr. Daniel A. Pontecorvo
President
90 South Newton Street Road, Suite 10
Newton Square, Pennsylvania 19073

Re: K133366
Trade/Device Name: Orthros Posterior Stabilization System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH, KWQ
Dated: March 6, 2014
Received: March 7, 2014

Dear Mr. Pontecorvo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133366

Device Name
Orthros Posterior Stabilization System

Indications for Use *(Describe)*
Orthros Posterior Stabilization System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral/iliac spine (T1-S1/Ilium): degenerative disc disease (defined as discogenic back pain with degeneration of disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

In addition, Orthros Posterior Stabilization System is intended for treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

James P. Bertram -S
2014.04.07 15:15:54 -04'00'

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."